UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

February 1, 2013

DP BARCODE:	406464
MRID:	48974100, 48974101, 48974102, 48974103, and 48974104
SUBJECT:	SP Ultra 8 Disinfectant Cleaner
REG. NO.:	9428-T
DOCUMENT TYPE:	Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
014703	7681-52-9	Sodium hypochlorite

TEST LAB:	Sun-Pine Corporation Gibraltar Laboratories, Inc.
SUBMITTER:	Sun-Pine Corporation
GUIDELINE:	Group A and B Product Chemistry
ORGANIZATION:	AD\PSB\CTT
REVIEWER:	Lynette T. Umez-Eronini
APPROVED BY:	Karen P. Hicks
APPROVED DATE:	February 1, 2013
COMMENT:	This product is for use on hard non-porous contact surfaces and nonporous non-food contact surfaces.

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February 1, 2013

MEMORANDUM

SUBJECT:	Product Chemistry Review for EPA Reg. 9428-T Product Name: SP Ultra 8 Disinfectant Cleaner DP Barcode: 406464
CODE:	A540 New Product; Non-Fast Track; FIFRA Sec. 2(MM) Uses;
DATE DUE:	April 15, 2013
FROM:	Lynette T. Umez-Eronini, Chemist Chemistry and Toxicology Team Product Science Branch Antimicrobials Division (7510P)
THRU:	Karen Hicks, Team Leader Chemistry and Toxicology Team Product Science Branch Antimicrobials Division (7510P)
TO:	Monisha Harris PM #32/David Liem Regulatory Management Branch II Antimicrobials Division (7510P)
Applicant:	Sun-Pine Corporation

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium Hypochlorite	8.25
Other Ingredient(s):	91.75
Total:	100.00

BACKGROUND:

The registrant, Sun-Pine Corporation, has submitted an application for registration of an end-use product called SP Ultra 8 Disinfectant Cleaner. The product is a cleaner, disinfectant, deodorizer and sanitizer for non-food use and for killing most germs and their odors. This product can be used on pre-cleaned hard non-porous surfaces and nonporous non-food contact surfaces. SP Ultra 8 Disinfectant Cleaner is produced by a non-integrated formulation system.

The original data package included:

1. Letters from Registrant to EPA, 10/15/2012 and 12/5/2012.
2. Application for Pesticide (8570-1), 10/15/2012.
3. Formulator's Exemption Statement (8570-27), 10/15/2012.
4. Basic Confidential Statement of Formula (CSF) (8570-37), 10/15/2012 and 12/5/2012.
5. Data matrix (8570-36), 10/15/2012, 2p.
6. Certification with Respect to Citation of Data (8570-34), 10/15/2012.
7. Proposed product label, 12/5/2012.
8. MRID 48974100: Transmittal Document dated 10/15/2012. Sun-Pine Corporation (2012) Submission of Product Chemistry and Efficacy Data in Support of the Application for Registration of SP Ultra 8 Disinfectant Cleaner. Transmittal of 12 Studies.
9. MRID 48974101: Courtney, M. (2012) Product Chemistry Data: SP Ultra 8 Disinfectant Cleaner. Unpublished study prepared by Sun-Pine Corporation. 10p.
10. MRID 48974102: Courtney, M. (2012) Product Chemistry Data: SP Ultra 8 Disinfectant Cleaner. Unpublished study prepared by Sun-Pine Corporation. 5p.
11. MRID 48974103: Courtney, M. (2012) Product Chemistry Data: SP Ultra 8 Disinfectant Cleaner Analytical Method. Unpublished study prepared by Sun-Pine Corporation, 5p.
12. MRID 48974104: Patel, M. (2012) EPA Product Chemistry on SP Ultra 8 Disinfectant Cleaner. Project Number R/268696/RO, GR/2886. Unpublished study prepared by Gibraltar Laboratories, Inc., 12p.

FINDINGS:

1. The Basic CSF, 12/5/2012 supersedes all previous CSFs.
2. From a chemistry point of view Reg No. 9428-T is a Me Too of Reg. No. 5813-100.
3. The active ingredient source is EPA registered.
4. The nominal concentration of the active ingredient on the Basic CSF is consistent with the label.

5. Group A product chemistry data requirements applicable to end-use products have been met (see MRID 48974101 and 48974103 and Table A below).

6. Group B product chemistry data requirements applicable to end-use products have been met (see MRID 48974102 and 48974104 and Table B below), with the exception of the OPPTS 830.6317 Storage Stability and 830.6320 Corrosion Characteristics studies.

RECOMMENDATIONS:

1. The registrant must submit a 1 year Storage Stability, 1 year Corrosion Characteristics study, both of which must include data at 0, 3, 6, 9, and 12 months.

CONCLUSION:

The Basic CSF, dated December 5, 2012 supersedes all previous CSFs and is acceptable. Group A Product Chemistry data requirements have been met. Group B Product Chemistry data requirements have been met with the exception of OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) studies. The unmet data requirements must be reported to the agency upon completion.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system — Yes [X] No [ ]
- Are all TGAIs used registered? — Yes [ ] No [X]
- Integrated formulation system — Yes [ ] No [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: 5813-100

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §180.940 and §180.950.

Yes [ ] No [X]

c. Physical state of product: Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient	NC(%)	LCL(%)	UCL(%)
Sodium Hypochlorite	8.25	10.31	8.25

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [ ]

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity	A	48974101
830.1600 Description of Materials	A	48974101
830.1620 Production Process	NA	
830.1650 Formulation Process[3]	A	48974101
830.1670 Formation of Impurities	NA	
830.1700 Preliminary Analysis	NA	
830.1750 Certified Limits	A	48974101
830.1800 Enforcement Analytical Method	A	48974101
830.1900 Submittal of Samples	A	48974101

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA	Gardner Color #3	48974102 48974104
830.6303 Physical State	A	Clear liquid solution	48974102 48974104
830.6304 Odor	NA	Mixed aromatic compounds	48974102 48974104
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		48974102
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A		48974102 48974104
830.6315 Flammability/ Flame Extension	A	>300°C (>572°F)	48974102 48974104
830.6316 Explodability	A		48974102
830.6317 Storage Stability	G	Study in progress	48974102
830.6319 Miscibility[1]	A	Immiscible in mineral oil.	48974102 48974104
830.6320 Corrosion Characteristics	G	Study in progress	48974102
830.6321 Dielectric Breakdown Voltage	A	Product is not used around electrical equipment	48974104
830.7000 pH[2]	A	12.6@ 25.0°C (77 F)	48974104
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity	A	Average 1.6891 cSt @ 20°C(68°F) 1.033 cST @ 40°C(104°F)	48974104
830.7200 Melting Point/Melting Range	NA		
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	A	Average Specific Gravity 1.1285	48974104
830.7370 Dissociation Constants in Water	NA		
830.7550/830.7560/830.7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water